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The Ambulatory O_2 Specialists!

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K042142

SEP 20 2004

SPECIAL 510(k)

510(k) SUMMARY

Chad Therapeutics, Inc.

Chad Therapeutics Lotus
(Modified Chad Therapeutics OXYMATIC Model 411)

Date Prepared:	August 6, 2004
Submitter Information:	Chad Therapeutics, Inc. 21622 Plummer Street Chatsworth, CA 91311
Official Contact:	Kevin McCulloh Vice President of Engineering
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E-mail:	kmcculloh@chadtherapeutics.com
Proprietary Names:	Chad Therapeutics Lotus Model OM-700 Chad Therapeutics Lotus Model OM-700S
Common Name:	Oxygen conserver
Classification Name:	Non-continuous ventilator
Classification Reference:	Class II, 21 CFR 868.5905
Product Code:	NFB

Predicate Device Equivalence:

Substantial equivalence is claimed to the Chad Therapeutics Unmodified OXYMATIC 411, cleared for commercial distribution per K003455.

Device Description:

The Chad Therapeutics Lotus is microprocessor-controlled device, which is a combination of a low-pressure regulator and an oxygen conserver, designed for use with ambulatory oxygen systems. It delivers boluses of oxygen that is equivalent to 1 to 6 liters per minute, depending on the flow rate setting.

Intended Use:

The Chad Therapeutics, Inc. Lotus is intended for prescription use only to be used as part of a portable oxygen delivery system for patients that require supplemental oxygen in their home and for ambulatory use.

Comparison of Technological Characteristics:

The Chad Therapeutics Lotus Model OM-700 and Model OM-700S has the same technological characteristics as the predicate devices. The hardware has been modified to reduce the size and weight of regulator portion. The software and electronics have been modified to include additional flow settings, a rechargeable battery pack circuit and for Model OM-700S the addition of a failure to pulse alarm. In addition the labeling has been modified. Major portions of the software and the patient inhalation detection sensor portion of the device are identical to the predicate device.

Summary of Testing:

All risk assessment, design verification and validation activities were conducted in accordance with the device product requirements to demonstrate that the Chad Therapeutics Lotus would perform as intended.

- ✓ The regulator in the device passed the ASTM PS 127-00 Promoted Ignition Safety Test.
- ✓ The Electromagnetic Compatibility, Electrostatic Discharge, Immunity, Magnetic Fields Immunity, Magnetic Fields Emissions, Quasi-Static Electric Fields, Radiated and Conducted Field Emissions, etc. were conducted in accordance with the specifications in the FDA Reviewer Guidance for Premarket Submissions, Anesthesiology and Respiratory Devices Branch, Division of Cardiovascular, Respiratory and Neurological Devices Document and applicable EN 60601 Medical Electrical Equipment specifications.
- ✓ The software complies with the applicable standards per the FDA Reviewers and Industry Guidance for the content of premarket submissions for software contained in medical devices.

Substantial Equivalence:

Based on the above, we concluded that the Chad Therapeutics modified OXYMATIC Model 411 (i.e., the Lotus Models OM-700 & OM-700S) are substantially equivalent to unmodified OXYMATIC 411 devices and are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 20 2004

Mr. Kevin McCulloh
Vice President of Engineering
Chad Therapeutics, Incorporated
21622 Plummer Street
Chatsworth, California 91311

Re: K042142
Trade/Device Name: Chad Therapeutics Lotus Models OM-700 and OM-700S
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: NFB
Dated: September 7, 2004
Received: September 13, 2004

Dear Mr. McCulloh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Chad Therapeutics Lotus Models OM-700 and OM-700S (modified Chad Therapeutics OXYMATIC Model 411)

Indications For Use:

The Chad Therapeutics Lotus (modified Chad Therapeutics OXYMATIC Model 411) is intended for use in the same manner as the unmodified device, i.e., for prescription use only, to be used as part of a portable oxygen delivery system for patients that require supplemental oxygen up to 6 liters per minute, in their home and for ambulatory use.

Prescription Use ___✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K042142